510k SUBMISSION **Falcon/Pro, Falcon/Quad, Falcon/ABI+** K111416

JUL 15 2011

SUMMARY

This summary of 510k safety and effectiveness information is being submitted in accordance with 21CFR part 807.92

1. Submitters name, address, phone number, contact person and preparation date:

Name: Viasonix Ltd
6B, Greenberg St.
Rannana , ISRAEL
Tel: 011 972 9 7441692

Responsible Person: Dan Manor

Official Correspondent:

William Stern
Multigon Industries, Inc.
1 Odell Plaza
Yonkers, N.Y. 10701
Phone: 914 376 5200 X27
Fax: 914 376 6111

Date of Preparation: May 17 , 2011

2. Device:

Proprietary Name: Falcon/Pro, Falcon/Quad, Falcon/ABI+

Common Name:
Classification Name: Transducer, Ultrasonic
Regulation Number: 21 CFR 870.2880
Classification Number: 90JOP

Manufactured By: Viasonix Ltd
6B, Greenberg St.
Rannana , ISRAEL
Tel: 011 972 9 7441692

3. Substantial Equivalency

Device Description:

The Falcon/Pro, Falcon/Quad, and Falcon/ABI+ systems are part of the Falcon product family of non-invasive peripheral vascular diagnostic systems. The Falcon/Pro is a complete peripheral vascular system that supports 10 independent pressure channels, 5 PPG sensors, 3 Doppler frequencies, and a temperature sensor. The Falcon/Quad and the Falcon/ABI+ systems are merely sub-assemblies of the Falcon/Pro system. Both support only 4 pressure channels, 4 PPG sensors and a temperature sensor. The Falcon/Quad also includes support for the 3 Doppler frequencies, while the Falcon/ABI+ does not support any Doppler features.

The Falcon/Pro and its' sub-assemblies Falcon/Quad and Falcon/ABI+ share the same hardware and software. While the main printed circuit board (PCB) is identical, the pneumatic components such as pumps, valves, sensors and check valves are assembled in the Falcon/Quad and Falcon/ABI+ to support only 4 pressure channels. In addition, one PPG sensor is omitted from the assembly of these systems. Furthermore, the Doppler board with its' PCB mount probe connectors is not assembled in the Falcon/ABI+ system. The same metal enclosure and connectors are used for the Falcon/Pro, Falcon/Quad, and Falcon/ABI+. The only difference lies in the front panel which is adapted according to the number of PPG sensors and Doppler probes.

The software level of concern for the Falcon products is determined as Moderate. The software of the Falcon/Pro, Falcon/Quad, and Falcon/ABI+ systems is practically identical. The only software differences are as follows: the Falcon/Pro supports 10 pressure cuffs (tubing marked in red, blue, green, yellow, orange, and white with lines in red, blue, green, yellow, and orange), while the sub-assemblies support only 4 pressure cuffs (tubing marked in red, blue, green, yellow); the Falcon/Pro supports 5 color coded PPG sensors (red, blue, green, yellow and black) while the sub-assemblies support only 4 such sensors (red, blue, green, yellow); the default examination protocols are adapted according to the supported sensors and probes; the maximal protocol group allowed with

the Falcon/Pro is 10, while the maximal allowed group for the sub-assemblies is 9; and the Falcon/ABI+ does not support any of the Doppler options and features.

All other software features are identical for the Falcon/Pro and the 2 sub-assemblies Falcon/Quad and Falcon/ABI+. Some of the main features include patient details and patient database management; Dicom connectivity; printing configuration and printing options; writing examination reports; summary screen support; configuration and management of examination protocols; measurement site configuration; export in various formats; import of VSX files; backup features; restoring backup data; online help options; and review stations. All of the standard signal control options and signal display options, as well as measurement calculations, are identical for all 3 systems (excluding Doppler related options for the Falcon/ABI+ system).

The quantitative measurements are the same for Falcon/Pro and the 2 sub-assemblies Falcon/Quad and Falcon/ABI+. The main measurement of the 3 systems is segmental systolic blood pressures. In general, the measurement is conducted by applying an appropriately sized cuff to the measured segment, obtaining a reference PPG or a Doppler signal in a location distal to the cuff placement, and then inflating the cuff to such a pressure that will occlude the blood vessels and prevent blood flow distal to the cuff location, which will result in disappearance of the reference signal. Then, a slow cuff deflation begins, and the instantaneous cuff pressure at which the reference signal reappears is typically defined as the segmental systolic blood pressure. While the software automatically places a cursor at the time location which is suspected as being the systolic pressure, it is the total responsibility of the system operator and the medical staff to modify the cursor location according to their medical training, and define the correct segmental pressure.

Based on the segmental pressures, the pressure indices are calculated, as the ratio between the systolic segmental pressure, and the higher of the 2 brachial systolic pressures. The ABI index is a commonly used index, which is a specific case of the above, calculated as the systolic right or left ankle pressure, divided by the higher of the right or left brachial systolic pressure.

The standard main Doppler parameters that are calculated (not for the Falcon/ABI+ system), include: *Mean*, representing the time-average value of the envelope (maximal velocity/frequency) over one cardiac cycle; *Peak*, representing the maximal systolic velocity/frequency during a cardiac cycle, in units of cm/sec or KHz; *Diast*, representing the minimal diastolic velocity/frequency during a cardiac cycle, in units of cm/sec or KHz; *PI*, representing the Gosling Pulsatility Index, calculated based on the peak envelope as (peak systolic velocity – minimal diastolic velocity) / mean velocity; *RI*, representing the Pourcelot Resistance Index, calculated based on the peak envelope as (peak systolic velocity – minimal diastolic velocity) / peak systolic velocity; *S/D*, representing the systolic to diastolic flow ratio, and is calculated based on the peak envelope as: (peak systolic velocity / minimal diastolic velocity); and *HR*, representing heart rate in beats (number of cardiac cycles) per minute.

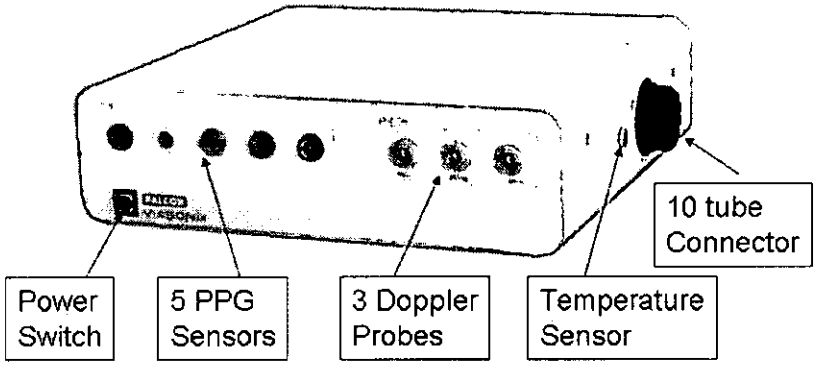
Additional parameters that are displayed are related to the specialty tests. During stress testing, a digital timer indicates the duration of the exposure to stress (for example the total time the patient exercised), and the recovery time for each measurement (the time that passed since the end of stress exercise and the current measurement). During venous reflux testing the system automatically places vertical cursors that denote the minimal PPG signal after sequential leg dorsiflexions and the point in time that the PPG signal returns to pre-dorsiflexion baseline. The time difference between these 2 cursors is calculated and referenced as the VRT (venous refill time). It is the responsibility of the examiner to determine the correct vertical cursor position, hence adjusting the VRT parameter. Likewise, the MVO/SVC ratio is based on the horizontal baseline and plateau signals, and the rate of signal drop immediately after rapid deflation of the thigh cuff. Again, it is the responsibility of the examiner to determine the correct cursor positions for the parameter calculation.

The Falcon complies with Class B EMC requirements. Therefore, the Falcon is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Device Components:

The main connectors on the front and right panels of the Falcon/Pro device are displayed in the picture below. These include the following:

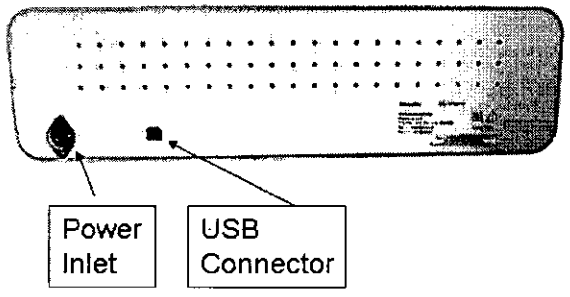
- Power switch, that is lit in green when turned on (on the front panel).
- 5 PPG connectors, color coded in red, green, blue, yellow and black (on the front panel).
- 3 Doppler probe connectors, with frequencies of 4, 8, and 10 MHz (on the front panel).
- A connector for 1 external skin temperature sensor (on the side panel).
- A connector for color coded 10 air tubes: red, blue, yellow, green, orange, red line, blue line, yellow line, green line and orange line (on the side panel).



The front panel of the Falcon/Quad is similar to the front panel of the Falcon/Pro, except that instead of 5 PPG sensor connectors it has only 4 PPG connectors (red, blue, green and yellow). Otherwise, the 3 Doppler probes and the power switch are identical. The side panel connectors are also identical to those included in the Falcon/Pro, except that only 4 color coded air tubes are connected (red, blue, green and yellow).

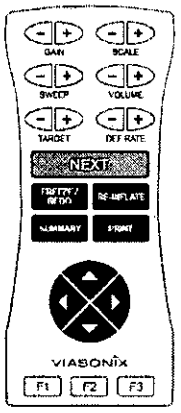
The front panel of the Falcon/ABI+ is similar to the front panel of the Falcon/Quad, i.e. it has only 4 PPG connectors (red, blue, green and yellow). An additional change is that it does not have any Doppler probe connectors. The power switch is identical to the Falcon/Pro and Falcon/Quad. The side panel connectors are similar to the Falcon/Quad, i.e. a temperature sensor and only 4 color coded air tubes are connected to the tube connector (red, blue, green and yellow).

The back panel for all Falcon devices is identical. It includes 2 connectors, one is the power inlet from the power supply, and the second is a USB connector to connect the Falcon to the host computer via a USB cable.



The Falcon devices connect to an approved 12 V medical power supply, which in turn connect to the mains power. All other supportive device components connect directly to the host computer. These include: multi-key wired remote control, 3-pedal foot switch, key-board, mouse, printer, and USB camera. Additionally, a 2-sided medical grade adhesive sticker is available to securely connect the disk PPG sensor or the temperature sensor to the skin at the site of measurement.

The remote control connects to the host computer via a USB connector. The remote control is designed for management of the most important Falcon functions and features that are used during an examination. In addition, it allows the user to operate away from the system, and by the patient bed. The remote control includes dedicated keys for most of the main functions, as well as some user defined keys. In general, there are four groups of keys in the remote control, as shown below: Signal Control Keys (with +/- options), Main Keys, Arrows, and Configurable Keys (F1-F3).



Predicate Device Comparison:

Feature	Vasoguard (Nicolet, Carefusion)	Multilab Series II (Unetixs)	Falcon/Pro	Falcon/Quad	Falcon/ABI+
510(k) number	K002766	K904392	this application	this application	this application
Indications for use	noninvasive evaluation of peripheral vascular pathology in patients	noninvasive evaluation of peripheral vascular pathology in patients	noninvasive evaluation of peripheral vascular pathology in patients	noninvasive evaluation of peripheral vascular pathology in patients	noninvasive evaluation of peripheral vascular pathology in patients
Pressure channels	10	10	10	4	4
Simultaneous PVR measurements	10	2	10	4	4
PPG sensors	4	2	5	4	4
Doppler probes	4 and 8 MHz CW	5 and 8 MHz CW	4, 8 and 10 MHz CW	4, 8 and 10 MHz CW	N/A
Temperature measurement	no	yes	yes	yes	yes
Specialty	stress,	stress,	stress,	stress,	stress,

tests	MVO/SVC, venous reflux, TOS	venous reflux, TOS	MVO/SVC, venous reflux, TOS	MVO/SVC, venous reflux, TOS	MVO/SVC, venous reflux, TOS
Remote control operation	yes, wired	yes, wireless	yes, wired	yes, wired	yes, wired
Touch screen controls	no	yes	yes	yes	yes
Foot switch controls	no	not known	yes	yes	yes
Mouse and keyboard controls	yes	yes	yes	yes	yes
Control of target inflation pressures	yes	yes	yes	yes	yes
Control of pressures deflation rate	no	yes	yes	yes	yes
Acoustic testing	track 1	not known	track 1	track 1	N/A
Doppler spectral analysis	yes, 128 point FFT	no	yes, 256 point FFT	yes, 256 point FFT	N/A
Bidirectional Doppler, invert function	yes	yes	yes	yes	N/A
Doppler volume controls	yes	yes	yes	yes	N/A
Doppler envelope	upper, lower, both, none	N/A	upper, lower, both, none	upper, lower, both, none	N/A
Calculated blood pressure parameters	ABI, segmental pressure indices	ABI, segmental pressure indices	ABI, segmental pressure indices	ABI, segmental pressure indices	ABI, segmental pressure indices
Calculated Doppler parameters	Peak velocity, mean velocity, diastolic velocity, PI, RI, systolic	none	Peak velocity, mean velocity, diastolic velocity, PI, RI, S/D, HR	Peak velocity, mean velocity, diastolic velocity, PI, RI, S/D, HR	N/A

	rise time				
Calculated venous reflux test parameters	Venous refill time	Venous refill time	Venous refill time	Venous refill time	Venous refill time
Calculated MVO/SVC test parameters	MVO/SVC ratio	N/A	MVO/SVC ratio	MVO/SVC ratio	MVO/SVC ratio
Backup options	NicVue	floppy disk	DVD, USB storage device	DVD, USB storage device	DVD, USB storage device
Dicom connectivity	available	available	available	available	available
Printer support	Most commercial printers	Most commercial printers	Most commercial printers	Most commercial printers	Most commercial printers
Customized examination protocols	available	available	available	available	available
Configuration of printed reports	available basic options	available basic options	available multiple options	available multiple options	available multiple options
Patient details	full, with patient history	basic	full, with patient history	full, with patient history	full, with patient history
Database search options	not known	By name, ID number and date	By name, ID number, date, and other examination details	By name, ID number, date, and other examination details	By name, ID number, date, and other examination details
Online help	no	not known	available	available	available
EMC Class	B	not known	B	B	B

4. Performance Standards:

No performance standards have been established for the Falcon/Pro, Falcon/Quad, Falcon/ABI+ under section 514 of the Federal Food and Drug Act. However the Falcon/Pro, Falcon/Quad, Falcon/ABI+ have been designed to meet the following main standards:

- EN 60601-1, Medical electrical equipment - Part 1. General requirements for safety (1990)

- IEC 60601-1-2, Medical electrical equipment - Part 1-2: Collateral Standard: Electromagnetic compatibility (2007).
- IEC 60601-2-37, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (2007-08).
- IEC 62304, Medical device software – Software life cycle processes (2006-05).
- ISO 14971, Medical devices — Application of risk management to medical devices (2007-10-01).

5. Indications for Use:

The Falcon/Pro, Falcon/Quad, and Falcon/ABI+ are intended for use in the noninvasive evaluation of peripheral vascular pathology in patients.

The devices are not intended to replace other means of evaluating vital patient physiological processes, are not intended to be used in fetal applications, and are not intended to be used inside the sterile field.

They are to be used by trained medical personnel in hospitals, clinics and physicians offices by prescription or doctor's orders.

6. Contra-Indications

None known at this time.

7. Comparison to predicate devices

The Falcon/Pro, Falcon/Quad, and Falcon/ABI+ products share similar device characteristics, intended use, performance, specifications and sensors, as other approved systems in the standard non-invasive diagnosis of peripheral vascular disease. The comparison table above details several of the key performance items with respect to the predicate devices Vasoguard (Nicolet, Carefusion) and Multilab II (Unetixs) systems that are commercially sold in the US and internationally.

In general, the Falcon product family (Falcon/Pro, Falcon/Quad, and Falcon/ABI+) and the predicate devices share common looks: a system casing, with variable connections to PPG sensors, Doppler probes (excluding Falcon/ABI+), and air tubes that connect to pressure cuffs. The Falcon products and the Vasoguard share the same 10-tube connector on the right side of the systems, that allows to easily disconnect all of the air tubes from the system. Display is via an external screen, and program controls in all systems can be carried out via key-board and mouse and remote controls, and in some systems additionally with touch screen and foot switch. In

addition, all of the systems (Falcon and predicate devices) use color coding to identify the different sensors and air tubes that lead to the pressure cuffs.

The Falcon products and the predicate devices are designed for use by experienced medical staff, in medical environments such as hospitals, clinics and physicians' offices. They share similar intended use, and a similar range of performance and specialty test options, including: segmental blood pressure measurements, segmental PVR (pulse volume recording) tests, PPG (photo-plethysmograph) tests, Doppler blood flow measurements, stress testing (measurement of the above tests following stress activity by the patient), venous reflux testing, impotence testing, MVO/SVC tests (maximal venous outflow / segmental venous capacitance), TOS tests (thoracic outlet syndrome), and other similar evaluations.

The Falcon products and the predicate devices are designed to provide both qualitative and quantitative information. The qualitative information mainly includes visual display of waveform shapes, including qualitative analysis of the PVR, PPG and Doppler waveforms. The quantitative information is focused primarily on aiding the examiners in obtaining systolic segmental blood pressures, and the corresponding segmental pressure indices including the ABI (ankle-brachial index). Additional quantitative measurements relate to the Doppler blood flow velocities and pulsatility indices, VRT (venous refill time) during venous reflux testing, and MVO/SVC ratio in the corresponding test.

The Falcon products and the predicate devices share similar signal and waveform controls, which directly affect both the signal and/or only the signal display. These controls include sweep time (controls the time axis display), scale (controls the Y axis display), gain (signal amplification), volume (Doppler audio sound level), target pressure (pressure level of initial cuff inflation), deflation rate (rate of cuff bleeding pressure (not for Vasuguard)), and signal filters (low pass and high pass).

In addition, the Falcon products and the predicate devices share similar standard features and options that are expected from such devices. These include: connection to external printers and report printing, management of patient database, offline review, routine backup of patient examinations, Dicom connectivity, summary examination screens, and configuration of examinations.

8. Test Data

The Falcon/Pro, Falcon/Quad, and Falcon/ABI+ range of non-invasive peripheral vascular diagnostic systems have been subjected to extensive safety, performance testing, and validation before release. Final testing of the Falcon/Pro, Falcon/Quad, and Falcon/ABI+ range of non-invasive peripheral vascular diagnostic systems included various performance testing that are designed to ensure that the devices meet all of their functional specifications. Safety and EMC tests have been performed by an approved laboratory to ensure that the devices comply with applicable industry and safety standards.

The Falcon/Pro, Falcon/Quad, and Falcon/ABI+ range of non-invasive peripheral vascular diagnostic systems labeling includes instructions for safe and effective use, warnings, cautions and guidance for use. In addition, all of the warnings, cautions, and instructions for use are provided by the program for immediate online review by the user. It is therefore shown to be safe and effective.

9. Literature Review

A review of the literature pertaining to the safety of the Falcon/Pro, Falcon/Quad, and Falcon/ABI+ range of non-invasive peripheral vascular diagnostic systems has been conducted and appropriate safeguards have been incorporated in the design of the Falcon/Pro, Falcon/Quad, and Falcon/ABI+ range of non-invasive peripheral vascular diagnostic systems.

10. Conclusions

The conclusion drawn from these tests is that the Falcon/Pro, Falcon/Quad, and Falcon/ABI+ range of non-invasive peripheral vascular diagnostic systems are equivalent in safety and efficacy to the predicate devices listed in the comparison table above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Viasonix, Ltd.
% Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

JUL 15 2011

Re: K111416
Trade/Device Name: Falcon/Pro, Falcon/Quad, and Falcon/ABI+
Regulation Number: 21 CFR 870.2880
Regulation Name: Ultrasonic transducer
Regulatory Class: II
Product Code: JOP
Dated: May 17, 2011
Received: May 20, 2011

Dear Mr. Stern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Falcon/Pro, Falcon/Quad, and Falcon/ABI+, as described in your premarket notification:

Transducer Model Number

4MHz CW
8MHz CW
10MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6542.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K111416

Device Name: ___ Falcon/Pro, Falcon/Quad, and Falcon/ABI+

Indications for Use:

The Falcon/Pro, Falcon/Quad, and Falcon/ABI+ are intended for use in the noninvasive evaluation of peripheral vascular pathology in patients.

The devices are not intended to replace other means of evaluating vital patient physiological processes, are not intended to be used in fetal applications, and are not intended to be used inside the sterile field.

They are to be used by trained medical personnel in hospitals, clinics and physicians offices by prescription or doctor's orders.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K111416

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: The Falcon/Pro, Falcon/Quad

Transducer: 4 MHZ CW

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				N			
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111416

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: The Falcon/Pro, Falcon/Quad
Transducer: 8 MHZ CW

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				N			
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111416

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: The Falcon/Pro, Falcon/Quad
Transducer: 10 MHZ

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				N			
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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510K K111416